

**SMG 1280.30**

**FDA Staff Manual Guides, Volume I - Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Pharmaceutical Quality**

**Office of New Drug Products**

Effective Date: September 25, 2019

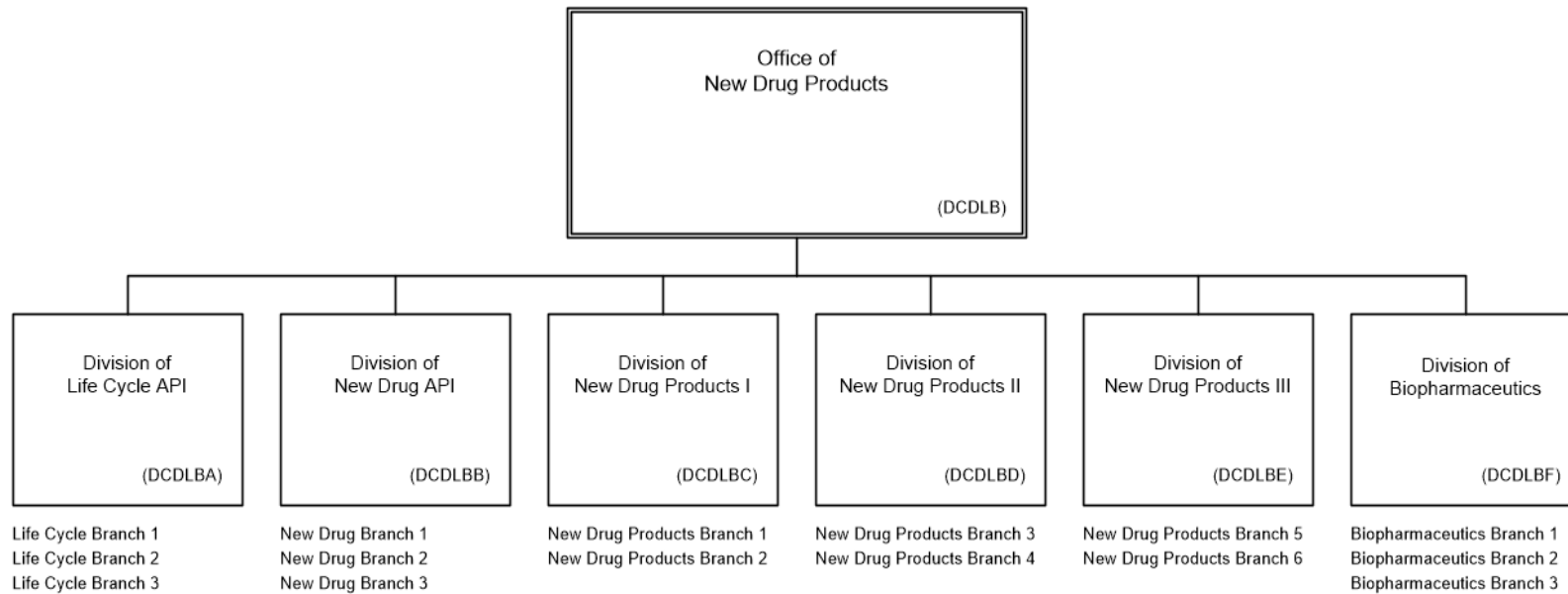
**1. Office of New Drug Products (DCDLB).**

- A. Conducts team-based, cross-office collaborative evaluation and assessment of Investigational New Drug (IND) and original New Drug Application (NDA) submissions, and Active Pharmaceutical Ingredient (API) information supporting Abbreviated New Drug Applications (ANDAs).
- B. Conveys risk-informed recommendations on the approvability of such products to appropriate stakeholders within Office of New Drugs (OND), other offices within Office of Pharmaceutical Quality (OPQ), industry, and is responsible for the communication of product-specific residual risk identified in the pre-marketing arena.
- C. Serves as a Liaison between OPQ and OND, works collaboratively with other OPQ offices to conduct application reviews and participates in inspections, as needed.

**2. Authority and Effective Date.**

The functional statements for the Office of New Drug Products were approved by Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services  
Food and Drug Administration  
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Office of Pharmaceutical Quality  
Office of New Drug Products**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of New Drug Products organizational structures depicting all the organizational structures reporting to the Director.

Office of New Drug Products (DCDLB).

These organizations report to the Office of New Drug Products.

Division of Life Cycle API (DCDLBA)

Division of New Drug API (DCDLBB)

Division of New Drug Products I (DCDLBC)

Division of New Drug Products II (DCDLBD)

Division of New Drug Products III (DCDLBE)

Division of Biopharmaceutics (DCDLBF)

These organizations report to the Division of Life Cycle API:

Life Cycle Branch 1

Life Cycle Branch 2

Life Cycle Branch 3

These organizations report to the Division of New Drug API:

New Drug Branch 1

New Drug Branch 2

New Drug Branch 3

These organizations report to the Division of New Drug Products I:

New Drug Products Branch 1

New Drug Products Branch 2

These organizations report to the Division of New Drug Products II:

New Drug Products Branch 4

New Drug Products Branch 5

These organizations report to the Division of Biopharmaceutics (DCDLBF):

Biopharmaceutics Branch 1 (DCDLBF1)

Biopharmaceutics Branch 2 (DCDLBF2)

Biopharmaceutics Branch 3 (DCDLBF3)

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